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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,336	10/01/1999	SUSAN LOVE	12.006011	6727
38732	7590	02/02/2005	EXAMINER	
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			RAWLINGS, STEPHEN L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/410,336	<b>Applicant(s)</b> LOVE ET AL.	
	<b>Examiner</b> Stephen L. Rawlings, Ph.D.	<b>Art Unit</b> 1642	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 10 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See attached Note of Explanation.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached Note of Explanation.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 33-39.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See attached Note of Explanation

LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER



### **Note of Explanation**

1. The amendment filed December 10, 2004 is acknowledged and has been entered. Claims 40-48 have been canceled. Claims 33, 37, and 39 have been amended.

2. Applicant's request for withdrawal of finality of the previous FINAL Office action is acknowledged. Applicant's arguments have been carefully considered but not found persuasive.

Regarding the propriety of setting forth new grounds of rejection in the FINAL Office action, the grounds set forth in the Office action mailed December 31, 2003 were rendered moot by Applicant's amendment of June 17, 2004, canceling all previously pending claims. The amendment added new claims 33-48. Accordingly, Applicant's amendment necessitated the new grounds of rejection. MPEP § 706.07(a) states: "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)."

Applicant has referred to § 706.07(a) as stating:

A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. See MPEP § 904 *et seq.* For example, one would reasonably expect that a rejection under 35 U.S.C. 112 for the reason of incompleteness would be replied to by an amendment supplying the omitted element.

Contrary to the example given in § 706.07(a), the nature of the changes made by the amendment filed June 17, 2003 would not have been reasonably expected, since it would not be reasonably expected that Applicant would cancel all previously pending claims and submit new claims, which although drawn to the elected invention, differ from the previously pending claims. For example, newly submitted claims were rejected

35 USC § 112, first paragraph, as failing to comply with the written description requirements, because the claims had a broader scope than previously examined claims, which was not properly and adequately supported by specification, including the claims, as originally filed. Such a change, which broadened the scope of the claimed invention, would not have been reasonably expected. Furthermore, new claims require a substantially more thorough examination than previously considered claims that have been amended, such that each and every change made, relative to their immediate prior version, is clearly marked. Had instead the previously pending claims been amended to incorporate the changes made in the newly added claims, relative to the prior version of the previously pending claims, the amendment *might* have obviated the previous grounds of rejection of those claims; but since all of those claims were canceled and new claims were added, such considerations were not made, as those grounds of rejection were rendered moot by the cancellation, and instead Applicant's submission of new claims necessitated a new search and new considerations, which provided the new ground of rejection set forth in the FINAL Office action.

Regarding the propriety of withdrawing claims 40-48 in the FINAL Office action, MPEP § 818.01 states, "[e]lection becomes fixed when the claims in an application have received an action on their merits by the Office". 37 CFR § 1.145 states: "If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144." As Applicant had already received an action on the merits for the originally presented invention, that invention had been constructively elected by original presentation for prosecution of the merits; as only claims 33-39 read on that invention, claims 40-48 were withdrawn from further prosecution. See MPEP § 821.03.

3. Entry of the amendment filed December 10, 2004 has obviated the following ground of objection or rejection set forth in the FINAL Office action mailed September 23, 2004:

(a) The objections to claims 37 and 39 for the reasons set forth in sections 7 and 8 of the Office action.

(b) The rejection of claims 33-39 under 35 USC § 112, first paragraph, for the reason set forth in section 10.

(c) The rejection of claim 36 under 35 USC § 112, second paragraph, for the reason set forth in section 12.

4. The following grounds of rejection set forth in the FINAL Office action have been maintained:

(a) The rejection of claims 33 and 36-39 under 35 USC § 103(a) for the reason set forth in section 14.

(b) The rejection of claims 34 and 35 under 35 USC § 103(a) for the reason set forth in section 15.

5. Applicant's request for reconsideration of the maintained grounds of rejection is acknowledged. Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has asserted that Yoshimoto et al. teaches away from the claimed invention, but Applicant has manipulatively taken the statement, "it is difficult to know the exact location of the disease within the breast from these images" out of context. The statement clearly addresses the inadequacy of mammography, not of the disclosed methodology.

Applicant has asserted that Canto et al. teaches that methylene blue does not selectively stain cancerous lesions. In reply, the reference is entitled: "Methylene blue selectively stains intestinal metaplasia in Barrett's esophagus".

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Applicant has again argued that methylene blue does not bind specifically to breast cancer cells. This argument has been addressed numerous times in prior Office actions.

Contrary to Applicant's arguments, the claimed invention is obvious over the combination of the teachings of the prior art of record.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
January 28, 2005



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER